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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,690

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Tero Soukka

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EXAMINER

YU, MELANIE J

ART UNIT

PAPER NUMBER

1641

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,690	<b>Applicant(s)</b> SOUKKA ET AL.	
	<b>Examiner</b> MELANIE YU	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/30</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 12 provides for the use of a nanoparticle, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.
2. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "minimum" is unclear because it is not adequately described. It is confusing as to whether the "minimum radius" is the radius from the center of the nanoparticle to the inner surface of the shell, whether it is the radius of the entire particle including the shell and binding moieties or whether the smallest radius of the particle is 10 nm and in this case it is unclear why there is an upper range of 40 nm.

### ***Claim Rejections - 35 USC § 101***

3. Claim 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kameda et al. (US 4,959,306).

Kameda et al. teach a nanoparticle comprising a self-assembling shell built up of several protein subunits of one type (apoferritin contains 24 protein subunits and is arranged as a spherical shell, which is a particle, col. 8, lines 65-67, although Kameda et al. do not specifically recite the particle being a nanoparticle, the particle is the same type, apoferritin, as that described in the instant specification and is therefore also a nanoparticle) assembled in an organized manner to form the shell having an inner surface facing the inside and an outer shell facing the outside of the particle (iron is removed from ferritin, which indicates that a portion of the apoferritin faces the inside of the shell and an outer portion faces the outside of the particle, col. 10, lines 38-48) wherein one of the types of subunits have a first binding moiety facing the outside of the particle for binding of any specific ligand binding protein (linkers specific to ferritin conjugated to apoferritin, col. 10, lines 55-68); and the particle contains attached to a type of subunit having a second binding moiety for binding a marker (Fab' fragments are labeled with fluorescein and attached to the particle, col. 11, lines 1-32); and the marker enables detection of the particle (fluorescein is used for detection, col. 11, lines 49-52) wherein the shell of the nanoparticle is an apoferritin-like particle (col. 8, lines 65-67).

With respect to claim 2, Kameda et al. teach the marker being fluorescein (col. 11, lines 1-32).

Regarding claim 10, Kameda et al. teach an apoferritin that is produced from a human liver ferritin (col. 10, lines 38-48), but do not recite the size of the apoferritin. However, the instant specification teaches an apoferritin produced from a human liver

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ferritin molecule in the background of the invention as having the necessary dimensions.

Therefore, the apoferritin molecule

With respect to claim 11, Kameda et al. teach the number of subunits being 24 (col. 8, lines 65-67), which encompasses the recited range of more than 20.

Regarding claim 13, Kameda et al. teach the nanoparticle of claim 1 and therefore teach a kit comprising the particle.

5. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kameda et al. (US 4,959,306), as applied to claim 2, in view of Bertozzi et al. (US 6,713,274).

Kameda et al. teach an apoferritin nanoparticle having a fluorescent marker that is fluorescein, but fail to specifically teach the marker being an enzyme or a lanthanide.

Bertozzi et al. teach that a detectable fluorescent marker may alternatively be fluorescein, luciferase or a lanthanide that is  $^{124}\text{Eu}$  (col. 10, lines 11-27), in order to provide a detectable label for detection of antibody binding.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute for the fluorescein marker taught by Kameda et al., a luciferase or lanthanide marker as taught by Bertozzi et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent labeling technique and since the same expected detection effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kameda et al. (US 4,959,306), as applied to claim 1, in view of Griffiths et al. (US 2003/0124586).

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Kameda et al. teach an apoferritin having two types of binding moieties, but fail to teach a third type of binding moiety facing the outside of the particle for binding to a solid support.

Griffiths et al. teach a binding moiety facing the outside of an apoferritin for binding to a solid support (par. 239), in order to provide linkage of a probe and target analyte to a substrate for detection.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include on the apoferritin nanoparticle of Kameda et al., a third binding moiety facing the outside of the particle for binding to a solid support as taught by Griffiths et al., in order to provide detection of binding that is localized to a specific area.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kameda et al. (US 4,959,306), as applied to claim 1, in view of Chandler et al. (US 6,599,331).

Kameda et al. teach a first and second binding moiety, but fail to teach the first binding moiety being protein A, protein G, protein L CBP or BCCP.

Chandler et al. teach that protein A is conjugated to a particle for attachment of a fluorescent label (col. 7, lines 42-65), in order to provide labeling or specific binding for a bead.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the first binding moiety of Kameda et al., a protein A conjugated to the particle as taught by Chandler et al., in order to provide sufficient and easy attachment of labels to the particle.

8. Claims 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kameda et al. (US 4,959,306), as applied to claim 1, in view of Bergmann et al. (US 6,537,760).

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Kameda et al. teach the first and second binding moiety being an antibody against CRP, ABO blood group antigens and TSH.

Bergmann et al. teach an antibody against TSH as a first specific binding moiety or to bind a label (antibody to TSH is immobilized to a particle and binds to TSH to detect a labeled TSH, col. 9, lines 5-12), in order to provide accurate detection of TSH.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the first or second moiety of Kameda et al., an antibody to TSH as taught by Bergmann et al., in order to provide an accurate indicator with greater clinical value for TSH which is detected to diagnose Graves' disease.

With respect to claim 10, a nanoparticle having these binding moieties and an apoferritin shell is the same as that recited in the claims and would therefore have the same size and radius properties as those recited in claim 10. Therefore, according to the instant specification, the nanoparticle taught by Kameda et al. in view of Bergmann et al. has a radius that is between 10 and 40 nm.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kameda et al. (US 4,959,306), as applied to claim 1, in view of Oon et al. (US 2003/0077578).

Kameda et al. teach a first and second binding moiety, but fail to teach the second binding moiety being protein A, protein G, protein L CBP or BCCP.

Oon et al. teach that protein A is conjugated to a support as a specific binding moiety (par. 96), in order to provide an antibody that binds immunoglobulins.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the first binding moiety of Kameda et al., a protein A conjugated to the particle as taught by McCormick et al., in order to separate any tagged target protein complexes from a sample for accurate detection.

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***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/  
Examiner, Art Unit 1641

/Long V Le/  
Supervisory Patent Examiner, Art Unit 1641